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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/683,656	10/09/2003	Sundeep Dugar	219002029600	2874

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MORRISON & FOERSTER LLP
12531 HIGH BLUFF DRIVE
SUITE 100
SAN DIEGO, CA 92130-2040

EXAMINER

CHANG, CELIA C

ART UNIT	PAPER NUMBER
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1625

MAIL DATE	DELIVERY MODE
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08/16/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/683,656

Applicant(s)

DUGAR, SUNDEEP

Examiner

Celia Chang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,6-10,12-14,16-18,20-24,28-30,33,39 and 42-45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1,39 and 42-45 is/are rejected.
- 7) ☐ Claim(s) 6-10,12-14,16-18,20-24,28-30 and 33 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Amendment and response filed by applicants dated Jun 11, 2007 have been entered and considered carefully. Claims 2-5, 11, 15, 19, 25-27, 31-32, 34-35, 37, 40-41 have been canceled. Claims 42-45 are newly added. Claims 1, 6-10, 12-14, 16-18, 20-24, 28-30, 33, 39 and newly added 42-45 are pending. Claims 36 and 38 stayed withdrawn.
2. Please note that the elected and examined subject matter is limited to $l=1$, $k=1$, Z^1 is N compounds. The restriction has been made final. It is recommended that the claims are limited to the elected and examined scope.
3. The rejection of claims 1-3, 12, 15, 19, 23, 26-27 under 112 second paragraph is moot in view of the cancellation and amendment of the claims. However, in the amended claim 1, the L^1 and L^2 being "linker" without limitation is confusing as to whether claims 8 and 9 were provided antecedent basis. It is recommended that description on page 6 be explicitly incorporated wherein L^1 or L^2 are CO, CH₂, SO, SO₂, CHOH; and L^2 can also be unsubstituted or substituted alkylene or akenylene wherein the substituents are those listed in claim 12.
4. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

This is a new matter rejection because the amendment wherein "one R1 is COCOR2 and the remaining R1(s) are hydrogen" lacks antecedent basis in the specification. Please note that on page 9 [0034], it was explicitly defined that the "doted line represents a double bond where the CR¹ in position 3 is that wherein R1 is WiCOXiY, preferably COCOR2, and CR¹ in position 2 is CH" and all the exemplified compounds have the COCOR2 at the 3-position. Such explicit disclosure is a *teaching away* from the amended negative limitation for which no antecedent basis was found.

Removal of new matter is required. In re Russmussen 210 USPQ 325.

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5. Claims 39, 42-45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims must under modern claim practice stand alone to define invention and *incorporation into claims by express reference to specification and/or drawings is not permitted* excepted in very limited circumstances. Ex parte Fressola 27 USPQ2d 1608. Please note that there is no good reason why the names or the chemical structure of the exemplified compounds cannot be incorporated into the claims.

6. Applicants attempted to amend claims 36 and 38. However, claims 36 and 38 cannot be rejoined because of 112 issues.

The claims encompassed tremendous number of compounds which have different chemical elements, linkage, bonding arrangements, size and properties for inhibiting p38 protein kinase activity. Enzyme inhibition requires specific binding which is very much like a lock and key situation, the key being the claimed compounds. Note that in re Fisher 166 USPQ 18-20 indicated that the more unpredictable the field of activity, the more enablement by way of specific examples is necessary in order to establish the broad scope of utility.

In the instant application only in vitro IC50 were disclosed with limited number of compounds. There is no nexus in the record that structurally similar compounds would have similar enzyme activity with demonstrated efficacy in any clinical conditions as listed in claim 38. Claim 38 encompassed enormously diverse and unrelated clinical conditions for which no single compound has been known to be responsive in treating all.

Claims 36 or 38 therefore cannot be rejoined with the compound claims.

7. It is recommended that the subject matter of claims 10 and 28 be incorporated into the base claims to obviate new matter.

Claims 6-9, 12-14, 16-18, 20-24, 29-30, 33 are objected to as being dependent upon a rejected base claim, but would be allowable when the 112 issues of the base claim is resolved.

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8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang, Ph. D. whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres, Ph. D., can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang
Aug. 14, 2007


Celia Chang
Primary Examiner
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